



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Box 25227, Bldg. 25
Denver Federal Center
Denver, CO 80225

DATE 7/29/2015

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Amy L. Juhnke, RQAP-GLP

INVESTIGATION ID NUMBER

20154954997

FIRM NAME AND ADDRESS: Bioscience Laboratories, Inc.
1765 South 19th Avenue
Bozeman, Montana 59718

FACILITY INSPECTED ADDRESS

Same.

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

For a FIFRA GLP inspection and audit of studies 130829-204,
140821-404.01, ^{P. M. Hualb} ~~104~~ 140525-204, 141111-204 and 120137-407.

- For study 120137-407 (ocular tissue study)
This study's compliance statement does not include all the differences between the study and the GLP Regulations as required by 160.12(b). For example this study did not have a formal GLP Protocol, or include a Quality Assurance Statement.

D.M.
7/29/2015

NOTE: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

ACKNOWLEDGMENT

THE UNDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

SIGNATURE

TITLE

MANAGER OF QUALITY ASSURANCE

PREPARED BY:

Daniel Myers

TITLE

Chemist / Inspector



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Box 25227, Bldg. 25
Denver Federal Center
Denver, CO 80225

DATE

Sept. 2, 2009

UNITED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

Dr. John Mitchell

INVESTIGATION ID NUMBER

20094954997

FACILITY NAME AND ADDRESS:

Bio Science Laboratories, Inc.

FACILITY INSPECTED ADDRESS

P.O. Box 190
300 N. Willson, Suite One
Bozeman, MT 59715

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Audit of four studies was completed: 47633609, 4647644211, 47644220, 47644221 and an on-going study not yet ~~sent~~ presented to the EPA. The on-going study is "090353-204 A Hand Surface Disinfection Evaluation of One Test Formulation Versus Six Bacterial and Yeast Species".

- No Findings were observed with respect to GLP ^{And} Books and Records issues.

E: This form provides only preliminary determinations by Agency inspectors. Final determinations concerning the number, nature and extent of violations will be made following enforcement review of the inspection report.

KNOWLEDGMENT

INDERSIGNED ACKNOWLEDGES RECEIPT OF A COPY OF THIS INFORMATION

ATTY:

John Mitchell

TITLE

Director of Quality Assurance

SIGNED BY:

Mark J. Lehr

Mark J. Lehr

TITLE

Chemist/Inspector



INSPECTION OBSERVATIONS

ADDRESS (EPA OFFICE)

HQ'OC

DATE

30 August 2001

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO:

Dr. John Mitchell

Daryl S. Paulson

TITLE

Pres/CEO

FIRM NAME AND ADDRESS

Bioscience Laboratories, Inc.

FACILITY INSPECTED ADDRESS

300 North Wilson, Suite 1
Bozeman, MT59715

DURING AN INSPECTION/AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

No negative observations

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ACKNOWLEDGEMENT

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SIGNATURE

Daryl S Paulson

TITLE

8-30-01

PREPARED BY:

JOHN D HELM III

John D. Helm III

TITLE

COMPLIANCE INSPECTOR/BIOLOGIST



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Office of Compliance
Bldg. 25, Box 25227, Denver Fed. Center
Denver, Colorado 80225

DATE

1/17/2012

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO:

Sherri Robbins

INVESTIGATION ID NUMBER

20122969579

FIRM NAME AND ADDRESS:

Nelson Laboratories, Inc.

FACILITY INSPECTED ADDRESS

6280 South Redwood Road
Salt Lake City, UT 84123

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Audited two studies 4751701, 47700403 : No negative findings observed
will report to GLP issues.

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SIGNATURE

TITLE

Director of Affairs

PREPARED BY:

Mark J. Lehr

TITLE

Chemist/ Inspector



INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE)

Box 25227, Bldg. 25
Denver Federal Center
Denver, CO 80225

DATE

March 24, 2004

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED
TO:

Dr. Jerry Nelson

INVESTIGATION ID NUMBER

20042969579

FIRM NAME AND ADDRESS:

Nelson Laboratories, Inc.

FACILITY INSPECTED ADDRESS

6280 South Redwood Road
Salt Lake City, Utah 84123

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

- No negative findings with respect to GLP issues.

The following studies were reviewed identified by MSD.

- 457753.01
- 457736.01
- 457736.02
- 457624.06
- 457624.07

In addition an ongoing study: Germicidal Spray test: Fungicidal
#250093 was also reviewed.

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ACKNOWLEDGMENT

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SIGNATURE

J. Nelson

TITLE

Lab Director (owner)

PREPARED BY:

Mark Lehr

M. Lehr

TITLE

Chemist/Inspector



INSPECTION OBSERVATIONS

INVESTIGATION ID: 200139695791

ADDRESS (EPA OFFICE)
1200 P st, Ave, NW
WASHINGTON, DC 20460

DATE
5/24/01

NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: DENNIS K. RANSOM

TITLE

VICE PRESIDENT,
ASSOCIATE LABORATORY DIRECTOR

FIRM NAME AND ADDRESS:

NELSON LABORATORIES, INC.
6280 SOUTH REDWOOD ROAD
SALT LAKE CITY, UT 84123-6600

FACILITY INSPECTED ADDRESS:

SAME

DURING AN INSPECTION/AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

No Negative Observations.

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ACKNOWLEDGEMENT

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SIGNATURE

Dennis Ransom

TITLE

ASSOC. LAB DIRECTOR

PREPARED BY:

John D. Helmer

TITLE

Compliance Inspector/Biologist